

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

ATTORNEY'S DOCKET NUMBER

525.1089-PCT-US

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

10/560,368

INTERNATIONAL APPLICATION NO.
PCT/US2004/018463INTERNATIONAL FILING DATE
10 June 2004PRIORITY DATE CLAIMED
11 June 2003

TITLE OF INVENTION

PHARMACEUTICAL DOSAGE FORMS HAVING OVERT AND COVERT MARKINGS FOR IDENTIFICATION AND AUTHENTICATION

APPLICANT(S) FOR DO/EO/US

KETTINGER, Frederick R.; FIELDS, Charles D. and FARRELL, Thomas P.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☐ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☐ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 23 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A power of attorney and/or change of address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
20. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
22. ☒ Express Mail Label No. **EV 685 805 113 US**

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO (if known, see 37 CFR 1.5) 10/560,368	INTERNATIONAL APPLICATION NO. PCT/US2004/018463	ATTORNEY'S DOCKET NUMBER 525.1089-PCT-US
23. Other items or information: Acknowledgment of Postcard Copy of Form PCT/DO/EO905		
The following fees have been submitted:		CALCULATIONS PTO USE
24. <input type="checkbox"/> Basic national fee	\$300	\$ \$0.00
25. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4). All other situations.	\$0 \$0 \$200	\$ \$0.00
26. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4). Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the as an International Searching Authority. International Search Report prepared by an ISA other than the US and provided to the previously communicated to the US by the IB. All other situations.	\$0 \$100 \$400 \$500	\$ \$0.00
TOTAL OF 24, 25 and 26 =		\$ \$0.00
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.		
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)
- 100 =	0 /50 =	0
x \$250.00		\$ \$0.00
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).		\$
CLAIMS	NUMBER FILED	NUMBER EXTRA
Total claims	- 20 =	0
x \$50.00		\$ \$0.00
Independent claims	- 3 =	0
x \$200.00		\$ \$0.00
MULTIPLE DEPENDENT CLAIMS (if applicable) <input type="checkbox"/> + \$360.00		\$ \$0.00
TOTAL OF ABOVE CALCULATIONS =		\$ \$0.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.		\$ \$0.00
SUBTOTAL =		\$ \$0.00
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).		\$ \$0.00
TOTAL NATIONAL FEE =		\$ \$0.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +		\$ 0
TOTAL FEES ENCLOSED =		\$ \$0.00
		Amount to be \$
		Amount to be \$

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 02-2275. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Michael N. Mercanti
LUCAS & MERCANTI, LLP
475 Park Avenue South
New York, New York 10016
Phone: 212-661-8000
Fax: 212-661-8002


SIGNATURE

Michael N. Mercanti

NAME

33,966

REGISTRATION NUMBER

April 20, 2006

DATE



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/560,368	Frederick R Kettinger	525.1089-PCT-US

20311
 LUCAS & MERCANTI, LLP
 475 PARK AVENUE SOUTH
 15TH FLOOR
 NEW YORK, NY 10016

RECEIVED
 WITH
 THANKS

APR 10 2006

LUCAS & MERCANTI LLP

INTERNATIONAL APPLICATION NO.
PCT/US04/18463
I.A. FILING DATE
PRIORITY DATE
06/10/2004
06/11/2003

CONFIRMATION NO. 5602

371 FORMALITIES LETTER



OC000000018465142

Date Mailed: 04/06/2006

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Indication of Small Entity Status
- Copy of the International Application filed on 12/09/2005
- Copy of the International Search Report filed on 12/09/2005
- Copy of IPE Report filed on 12/09/2005
- Preliminary Amendments filed on 12/09/2005
- Information Disclosure Statements filed on 12/09/2005
- Oath or Declaration filed on 12/09/2005
- Request for Immediate Examination filed on 12/09/2005
- U.S. Basic National Fees filed on 12/09/2005
- Priority Documents filed on 12/09/2005

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
 - is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

SHAKEEL AHMED

Telephone: (703) 308-9140 EXT 208

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/560,368	PCT/US04/18463	525.1089-PCT-US

FORM PCT/DO/EO/905 (371 Formalities Notice)